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Development and preliminary evaluation of tablet computer-based decision aid for patients participating in cancer clinical trials

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ABSTRACT

Objectives: Patients often consent to participate in cancer clinical trials despite misunderstanding the trial content. We developed a tablet-based clinical trial decision aid and tested its use with the usual discussion at the time of clinical trial registration.

Methods: Participants were individuals considering participating in a breast cancer clinical trial. The control participated in usual discussions; the intervention group participated in discussion using the decision aid. Pre- and post-discussion, we investigated knowledge, decision-making conflict, and discussion length.

Results: We enrolled 54 patients, 27 in the control group and 27 in the intervention group. Post-discussion clinical trial knowledge was significantly higher in the intervention group than in the control group ($p = 0.003$). No significant difference was found in decisional conflict, but the intervention group tended to have lower post-discussion conflict than the control group. There was no between-group difference in the length of discussions with physicians and clinical research coordinators.

Conclusion: For women considering participation in cancer clinical trials, a tablet-based decision aid may promote clinical trial understanding without increasing discussion length or patient burden. This pre-learning decision aid incorporating a quiz and bidirectional question prompt lists may improve participants' understanding of clinical trials.

1. Introduction

Clinical trials that are conducted for drug approval applications and expansion of indications are regulated by the Good Clinical Practice (GCP) standard [1]. As the GCP specifies that a clinical trial agreement explanation document must include 20 components, this document contains a large amount of information. Physicians in charge of clinical trials must appropriately explain the trial in writing in terms that potential participants can understand, and must obtain participants' consent. In addition, physicians and clinical research coordinators (CRCs) must usually obtain consent from patients in the limited time available between consultations.

Advances in diagnostics and treatment mean that information about cancer tests, treatments, and clinical trials is more complex. Indeed, many cancer clinical trial participants take part in clinical trials despite misunderstanding aspects of the trial such as study treatment assignments, possible adverse events, and the presence of non-research treatment options [2–4]. There is also evidence that participants' perceptions of their own understanding may not match their actual understanding [5,6]. As a result, it is difficult for medical professionals to objectively determine to what extent participants understand their explanations [4,7]. Clinical trial participants with poor understanding are less satisfied with their decisions and experience greater conflict and regret after the trial [8]. In cancer clinical trials, there are treatments such as oral anticancer drugs for which the patient's adherence has a significant impact on the treatment effect. In such clinical trials, the patient's understanding of the treatment will directly affect the quality of the trial. Poor understanding may lead to dropout in the middle of clinical trials, and may adversely affect participants.

In response to concerns about insufficient understanding in clinical trial participants, some researchers have developed educational materials that utilize audiovisual functions, such as videos, and have attempted to improve explanation documents and pamphlets [9–14]. The booklet, designed to meet the International Patient Decision Aid Standards (IPDAS) criteria, improved knowledge, decisional conflict and anxiety about clinical trials [14]. The audio-visual presentation also improved knowledge and satisfaction with the information [13]. The test/feedback approach made a significant improvement in

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understanding [12]. Tools that utilize interactive functions improved treatment understanding and compliance and reduce conflict, regret, and depression during treatment [9]. There is active research and development of decision aids in various fields, such as treatment and examination, and there has been progress in the definition and evaluation of decision aids [9,11]. However, despite recognition of the importance of decision support, there are few studies in the field of clinical trials [12–14].

In recent years, information and communication technology has advanced substantially; mobile phone ownership and the Internet penetration rate have dramatically increased. Technological functions are now highly developed, and many devices can be operated intuitively using touch panels. One example is tablet terminals, which have excellent portability and can provide information utilizing audiovisual and interactive features. These can be used in medical applications in various ways. In the field of clinical trials, efforts have begun to investigate patient-reported outcomes (e.g., quality of life) using methods such as tablet terminals [15]. These devices have the potential to support decision making more effectively.

The purpose of this study was to develop a tablet terminal application to enable decision-making with better understanding and acceptance to prevent disadvantages for participants and poor quality of clinical trials. The effect of the application was preliminarily evaluated in terms of clinical trial understanding, decisional conflict in decision making, and explanation time.

2. Methods

This study was conducted as part of the clinical trial "S-1 postoperative randomized controlled phase III trial for estrogen receptor-positive HER2-negative breast cancer." The aim of the trial was to test the effect of standard postoperative endocrine therapy and oral anticancer drug S-1 compared with standard postoperative endocrine therapy alone, targeting primary estrogen receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative primary breast cancer. This was a randomized controlled trial investigating whether the recurrence suppression effect is enhanced by combined therapy with oral administration. Eligibility criteria were (1) Stage I to IIIA and stage IIIB histological invasive ductal carcinoma, (2) Diagnosis made at the first medical examination and scheduled for radical surgery, (3) Estrogen receptor-positive, HER2 negative, (4) Positive axillary lymph node metastasis; alternatively, negative axillary lymph node metastasis and intermediate/high risk of recurrence, (5) Age at registration of 20–75 years. Study participants were individuals who planned to enroll in the clinical trial. From women who visited a mammary department outpatient clinic at four institutions conducting this clinical trial between June and November 2013, we recruited those who could understand Japanese and could make independent decisions. All four facilities were cancer center hospitals and were undertaking numerous clinical trials.

This study was nested into the clinical trial that was organized as an RCT. We were concerned that explaining the other RCT in addition to explaining the clinical trial would confuse the patients. Therefore, this study was designed as a quasi-experimental study. Participants registered in the first half of the recruitment period of June–August 2013 were allocated to a control group for usual discussion; participants registered from the latter half of September to November 2013 were allocated to an intervention group for discussion using the decision aid. The sample size was calculated in a *t*-test of the difference in means for the knowledge of clinical trials. The effect size was set at 0.4 (Cohen's d), two-sided alpha 0.05, and power 0.8 from a previous study [14]. The calculated sample size was 100 participants in each group. This study was conducted as a preliminary study with a total of 54 participants, 27 from each group who cooperated during the recruitment period.

2.1. Application development

The application configuration comprised a learning function to support people considering participation in cancer clinical trials. The application was designed to support participation decision making by providing accurate information, and included a communication support function to facilitate smooth and effective communication. The structure of the decision aid was created in accordance with the International Patient Decision Aid Standards [11]. A working group with study drug developer, CRCs, two mammologists, and the principal investigator, one Breast cancer patients, communication scholars, statisticians, and ethicists as members developed the application.

The content consisted of 11 items (research purpose, tumor characteristics, clinical trials, outline of the clinical trial. standard treatment effects and side effects, trial treatment effects and side effects, treatment allocation method, treatment period, cost burden, withdrawal of consent, and handling of personal information). These include all of the "contents to be included in explanations and documents" listed in the Informed Consent section of the ICH GCP and the Japanese Ministerial GCP. The items were expressed in easy-to-understand text accompanied by illustrations and photographs. If the participant tapped on a medical term, a simpler explanation of the term popped up. To help participants understand the content, each item was associated with a quiz. In order to assist in value-based decision making, the advantages and disadvantages of participating in clinical trials were presented as graphs with verbal explanations of the probabilities, and the future course of treatment was presented on both sides, with and without participation. At the end of the text, we added a patient question list (PQL), which allowed users to directly inform their medical staff of any questions they would like to ask, and a response item on which participants could indicate their intention to participate in the clinical trial [16]. The results were displayed on the administrator's screen, helping physicians and CRCs to provide explanations based on participants' level of understanding and information needs. The users can go back to the page as many times as they want to check the contents, participate in the quiz, and change their participation decision. To ensure content accuracy and consistency with the consent form, the content of the information posted on the application was confirmed by the two CRCs and five mammologists. In addition, the application was evaluated by two mammologists, an ethicist, and two CRCs to ensure that it met the criteria for decision aids. After the intervention study, the International Patient Decision Aid Standards instrument (IPDASi) v4, a standard for decision aids, provided by the International Patient Decision Aid Standards, was released, and we evaluated the results based on this standard. All raters evaluated the quality criteria as meeting all six criteria, and all six certification criteria had a rater mean of 3 or higher. Of the 23 items in the quality criteria, 15 items were judged to meet the criteria of 3 or higher by all raters. Of the 23 items in the quality criteria, 15 items were judged by all raters to meet the criteria of 3 or higher, indicating that this application meets the criteria for Decision Aids. The application was developed to be used on a mobile information terminal equipped with Android OS 4.2. Participants used a tablet terminal equipped with a 10-inch display. To simplify use, the application was designed to be operated only by tapping, rather than using complicated operations such as pinch and swipe. The general clinical trial section of the application can be used directly for other clinical trials. There is also a section describing diseases and treatments related to the clinical trial, which can be added to other clinical trials by creating a new page for that trial.

2.2. Pilot test

After completing the prototype, we conducted a pilot test with 10 Breast cancer participants. Two CRCs provided applications and discussions to the participants, just as they would in an actual clinical trial briefing. The participants evaluated the content, saying that they were able to organize their thoughts based on prior knowledge, and that they

were able to make thoughtful decisions versus being able to consult with the medical staff after expressing their intentions in advance outside of their presence. Final adjustments were made to the contents and specifications based on the participants' opinions. For example, we expanded the pop-up descriptions for terms that were difficult to understand, and changed the font size from 16 points to 18 points or above.

2.3. Data collection and intervention

Physicians informed the patients about present study as well as the clinical trial during consultations. To avoid confusion in explaining the patient about the two studies, the present study and the clinical trial, the present study was a non-randomized controlled trial. Patients who agreed to participate in the study completed a baseline questionnaire. Subsequently, participants allocated to the control group received an explanation of the clinical trial details from the physician and CRC as usual, in line with the clinical trial agreement explanation document. Participants allocated to the intervention group received the application developed in this study together with the clinical trial document. Both intervention and control participants also subsequently received a written explanation of the trial. Both groups had the opportunity to discuss the trial with their physician and CRC after receiving the explanation. All participants reported to their physicians whether or not they wished to participate in the clinical trial 3 weeks after the initial survey, at which time they completed a second questionnaire. All questionnaires used in this research were paper versions, and were distributed and collected by the CRCs of each facility. CRCs were available to provide explanations to registrants for more than 1 year after starting the clinical trial. All CRCs conducting the briefing participated in a 2-h pre-briefing by the researcher. The same materials and methods were used to ensure that there were no differences in explanation procedures or content between sites.

2.4. Measurement

At baseline, we surveyed the sociodemographic characteristics of age, educational background, employment status, mobile phone usage, and Internet usage. The Functional, Communicative, and Critical Health Literacy (FCCHL) scale was also used to assess literacy of breast cancer and clinical trials [17]. This scale consists of 14 items scored on a four-point scale. The total score range is 4–56; higher scores indicate greater literacy.

2.4.1. Knowledge of the clinical trial

Drawing on the Quality of Informed Consent (QuIC) measure developed by Joffe et al. working group developed a Japanese version questionnaire to assess clinical trial knowledge [7,18]. The questionnaire comprises 25 questions: 5 four-choice questions on tumor characteristics, 10 four-choice questions on this clinical trial, and 10 true/false questions on clinical trials in general. Ten participants in the pilot study pre-tested the questionnaire to ensure that the content was easy to understand and that there were no problems with comprehension. To check the retest reliability, the participants answered the questionnaire twice; the ICC was 0.68. Questions are scored on a two-point scale. The total possible score range is 0–100. This questionnaire was administered at baseline and 3 weeks after the intervention.

2.4.2. Decisional conflict

The Decisional Conflict Scale (DCS) was used to evaluate psychological conflict in decision making [19]. This scale consists of 16 items scored on a five-point scale (0 = strongly agree to 4 = strongly disagree). A Japanese version of the scale has been developed and evaluated for validity and reliability [20]. The scale measures how uncertain (3 items) the current decision is, and the following factors that contribute to that uncertainty: feeling informed, clarity of personal values, and feeling supported (3 items each). The scale also measures effective decision making (4 items); that is, recognition of the quality of decision making. The total scale score comprises the sum of the corresponding item scores divided by the number of items, and ranges from 0 to 100. Scores of 25 or less indicate a state of low conflict; scores over 37.5 indicate a state of high conflict. The scale was administered at baseline and 3 weeks after the intervention.

2.4.3. Application usability and discussion time

We created a 15-item scale based on the Web Usability Scale (WUS) developed by Nakagawa [21]. The original WUS consists of 21 items rated on a five-point Likert scale. The scale was developed to evaluate websites. In the present study, six of the original items were excluded because they were judged unnecessary for the evaluation of this application. We evaluated how much participants liked the application, the usefulness of the application, the intelligibility of the operation method and configuration, and ease of viewing. The purpose of this questionnaire was to evaluate the user interface of the application. Therefore, the evaluation was conducted immediately after the use of the application, when the user would remember the feeling and experience of using the application. The length of discussion time with physicians and CRCs was recorded to evaluate whether the application had an effect on the length of discussion time.

2.5. Ethical considerations

All study participants provided written informed consent, and the study design was approved by the ethics committee of the University of Tokyo Medical School Ethics Committee and institutional review board (No. 10076).

2.6. Data analysis

Descriptive statistics were calculated for the baseline background data, FCCHL score, and the time required by the physician/CRC to explain the trial. To compare between groups and to confirm the balance of each group, the *t*-test was conducted for continuous variables, and Fisher's exact test used for categorical variables.

To analyze participant knowledge and DCS score, the paired *t*-test was used to compare scores before and after the intervention for each group. In addition, a *t*-test was performed on the between-group score difference after the intervention and the score difference before and after the intervention in each group. For both scores, the intervention group tended to have lower or higher pre-intervention values than the control group; therefore, a covariance analysis was performed using the pre-/post-intervention differences as dependent variables and pre-intervention values as a covariate. For the knowledge score, the interaction term was not included in the model because no interaction was detected between the pre-intervention value and the effect of the intervention. A usability test summarized the results of each item.

All tests were two-sided with a significance level of 5%. SAS software version 9.3 for Windows (SAS Institute Inc., Cary, NC, USA) was used for analysis.

3. Results

Participants were recruited between June and November 2013. A total of 62 clinical trial participants visited four hospitals and 54 (87%) women consented to participate in this study. Of these, 27 were assigned to the control group and 27 to the intervention group. All participants responded to the baseline and post-intervention questionnaires, and all those assigned to the intervention group received the application-based intervention (Fig. 1). The number of participants in each facility was 9 in facility A, 4 in facility B, 8 in facility C, and 6 in facility D for the intervention and control groups, respectively.

Table 1 shows the characteristics of the 54 participants. There was no significant difference in the distributions of the control and intervention

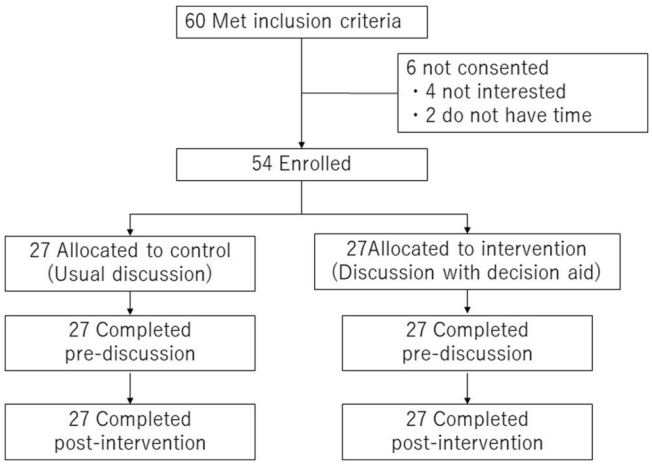

Fig. 1. Study flow chart.

Table 1
Characteristics of study participants.

	Intervention (n = 27)		Control (n = 27)	
	n	%	*n*	%
Age				
Mean, SD	48.4	6.0	50.3	8.5
Sex				
Male	0	0.0	0	0.0
Female	27	100.0	27	100.0
Education				
Junior high school	1	3.7	1	3.7
High school	9	33.3	11	40.7
College	11	40.7	12	44.4
University or Graduate school	6	22.2	3	11.1
Employment				
Full-time	14	51.9	18	66.7
Other	13	48.2	9	33.3
Household income (million yen)				
3	2	7.7	3	11.1
≥3 and < 5	4	15.4	6	22.2
≥5 and < 7	2	7.7	6	22.2
≥7 and < 9	5	19.2	3	11.1
≥9	7	26.9	5	18.5
Smartphone user				
Yes	14	51.9	12	48.0
No	13	48.2	13	52.0
Health literacy (FCCHL)				
Breast cancer	41.9	3.9	40.7	5.9
Clinical trial	38.6	6.1	36.3	5.5

a Calculated using *t*-test.
b Calculated using chi-square test. SD = standard deviation, FCCHL= Functional, Communicative, and Critical Health Literacy scale.

groups. The mean age of participants was approximately 50 years (range: 38–70 years), and 86% were younger than 60 years. The mean number of days between completing the baseline questionnaire and completing the post-intervention questionnaire (at the time of decision making) was 23 days (standard deviation [SD], 8.1 days) for the control group and 19 days (SD, 8.9 days) for the intervention group, but there was no significant between-group difference. FCCHL scores did not differ between groups, but both groups tended to have lower clinical trial literacy than breast cancer literacy.

Regarding clinical trial knowledge, post-discussion scores were higher than pre-discussion scores in both groups (Table 2). In the intervention group, the score after explanation was significantly higher than that at baseline ($p < 0.001$), and the differences between before and after the intervention were statistically significant compared with the change in the control group ($p = 0.003$). Because the baseline score tended to be lower in the intervention group than in the control group ($p = 0.053$), a covariance analysis adjusted for baseline score was performed. This showed a statistically significant difference between the control group and the intervention group ($p = 0.03$). Analysis of variance for pre/post differences in Knowledge scores between facilities showed no statistically significant differences ($p = 0.274$).

DCS scores tended to be lower after the intervention compared with baseline in both groups (Table 3). As baseline DCS scores were significantly higher in the intervention group than in the control group, a covariance analysis adjusted for baseline score was performed. This showed no significant difference between the changes in both groups ($p = 0.391$). A comparison of scores for each DCS factor showed a greater decrease on most factors in the intervention group compared with the control group, although the differences were not significant. Analysis of variance for pre/post differences in DCS scores between facilities showed no statistically significant differences ($p = 0.607$).

The mean time required by physicians to discuss the clinical trial was 7 min (SD, 3.0) in the control group and 6 min (SD, 3.3) in the intervention group, and there was no significant between-group difference. The mean CRC discussion time was 19.1 min (SD, 13.7) in the control group and 15.1 (SD, 18.8) in the intervention group; the between-group difference was not significant.

The mean number of page transitions by participants using the application was 65.7. The mean time required to use the application was 11 min (minimum, 8 min; maximum, 16 min). The results of the usability survey showed that all participants liked the application, found it useful, found the operation method and configuration intelligible, and found it easy to view. No correlation was found between application usage time and background factors such as age, smartphone or tablet use, or Internet use.

4. Discussion and conclusion

4.1. Discussion

In this study, we developed a self-learning application to facilitate the explanation of a cancer clinical trial in a limited time and to make participant decision making more efficient and effective. We tested the effect of the application on participant knowledge, decision-making conflict, time required for explanation, and usability. The findings suggested that this application may help women who are considering participating in cancer clinical trials to understand the clinical trial and reduce decision-making conflict. The results also indicate that the application could be used in clinical settings.

Table 2
Comparison of clinical trial knowledge between intervention and control groups.

		Intervention (n = 27)						Control (n = 27)						p[a]
		Pre		Post		Difference		Pre		Post		Difference		
	Range	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Clinical trial knowledge	0–100	64.4	14.4	81.1	9.8	16.7	10.9	66.2	11.8	76.1	11.1	9.9	11.8	0.020

Knowledge of the clinical trial: higher scores indicate greater knowledge. Pre = before discussion, Post = 3 weeks after discussion (at the final decision), SD = standard deviation.
[a] Calculated using covariance analysis with pre-discussion score as covariate.

Table 3
Comparison of decisional conflict about clinical trial participation between intervention and control groups.

		Intervention (n = 27)						Control (n = 27)						p[a]
		Pre		Post		Difference		Pre		Post		Difference		
	Range	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Total Score	0–100	39.8	18.5	31.9	12.2	−7.8	12.6	42.4	10.3	35.5	11.7	−6.9	11.4	0.391
Uncertainty	0–100	42.0	21.9	36.4	18.4	−5.6	18.9	51.9	17.2	43.2	18.2	−8.6	16.7	0.702
Informed	0–100	39.5	22.5	33.0	12.3	−6.5	18.4	40.7	16.6	34.0	13.9	−6.8	21.6	0.845
Value	0–100	43.2	18.2	35.8	16.3	−7.4	14.9	43.8	16.6	37.3	13.7	−6.5	17.0	0.772
Support	0–100	39.8	22.3	28.4	16.9	−11.4	20.2	40.4	11.9	31.2	15.6	−9.3	13.3	0.521
Effectiveness	0–100	35.6	20.1	27.6	16.4	−8.1	16.1	36.8	13.8	32.6	11.1	−4.2	13.0	0.124

DCS = Decisional Conflict Scale (lower scores indicate lower conflict), Pre = before discussion, Post = 3 weeks after discussion (at the final decision), SD = standard deviation, Uncertain = uncertainty about the current decision, Informed = feeling informed, Value = clarity of personal values, Support = feeling supported, Effectiveness = recognition of the quality of decision making.

[a] Calculated using covariance analysis with pre-discussion score as covariate.

Although it is not easy to understand the details of clinical trials, it is important to ensure that potential participants understand important issues, such as the treatment, typical risks, and ways of withdrawing consent. However, the control group's knowledge scores indicate that when participants received the usual explanation, their understanding before trial participation was approximately 70%. This is similar to the results of previous studies and may indicate the limits to which clinical trial participants can understand clinical trials with the usual written explanations [1,2]. Knowledge of the clinical trial contents was significantly higher in the intervention group, which received an explanation using the application developed in this study. This may be because a quiz was included in the application. The quiz was inserted into the middle of the explanation, and enabled users to proceed to the next explanation after checking that they had correctly understand the contents so far. The use of the quiz also helped to avoid monotonous, text-only explanations. Previous studies in other fields have reported that incorporating quizzes into decision-support tools increases understanding and long-term knowledge retention [22,23]. Well-understood participation in clinical trials and less conflicted decision making will improve compliance to clinical trials and treatments [9].

The intervention group tended to be able to make decisions with less conflict than the control group. This result is consistent with a previous research report that the degree of psychological decision-making conflict decreases as knowledge of the target event increases [24]. In addition, although there was no between-group difference in physician/CRC explanation time, the intervention group scored better than the control group on the DCS factor that assessed the satisfaction with healthcare provider support for decision making. This application may not contribute to reducing the amount of time required by physicians and CRCs for explanations, but the same length of time will result in higher understanding and higher satisfaction in the decision to participate.

The PQL provided at the end of the application allows the user to inform the healthcare provider of any questions they had while using the application. This may allow doctors and CRCs to obtain information tailored to patients' individual needs, which may help patients recognize that they have received sufficient support. Most participants in the intervention group had more than one PQL checked in the application, although there were few questions from the participants in the control group, who received the usual explanation. The effectiveness of PQL in doctor–patient communication has been reported in previous studies; patients do not always ask what they want to ask, or do not know what to ask [25–27]. In addition, shared decision making, in which patients actively participate in treatment decision making as well as physicians, affects satisfaction with decision [28]. Therefore, PQL may be an effective tool for supporting communication about clinical trials and communication in clinical situations between healthcare providers and participants.

As indicated by the health literacy score, these breast cancer clinical trial participants tended to have greater knowledge of breast cancer than of clinical trials. This indicates that participants have different attitudes toward clinical trial information than they do toward information about their disease. Healthcare providers who explain clinical trials need to understand that clinical trial information is more unfamiliar and difficult for patients to understand than disease information. Additionally, healthcare providers need to take great care to ensure that patients fully understand the information provided.

Although more than half of participants were not smartphone and tablet users, all answered that they liked the application, that the operational method was easy to understand, and that it was easy to view. This application has a simple specification that can be operated simply by tapping, with none of the complicated operations unique to touch panels, such as pinching and swiping. In response to tapping, some areas expanded to provide more information. These features ensured that even participants unfamiliar with touch panel devices could use this tablet device application with no problems.

These findings must be interpreted in light of several limitations. The sample size may have been insufficient to detect a meaningful difference. As this was not a randomized trial, confounding variables may have affected the data. In addition, all participants were women and 86% were in their 40s or 50s; therefore, the effect of the application on men and older people should be investigated. This study was conducted in 2013, and the application was developed with reference to the laws and findings at that time. If there are any changes in laws and regulations related to clinical trials, this study should be interpreted against the new information.

All sites included in the study had extensive experience in clinical trials and were staffed by CRCs. However, the need for such tools for efficient and high quality decision making is greater at sites where only physicians are conducting clinical trials. In the future, we hope that the utility of this tool will be recognized in a variety of clinical settings.

4.2. Conclusions

Our findings suggest that tablet-based decision aids can be useful in facilitating clinical trial understanding in the discussion of female cancer clinical trials. Such decision aids can be used without disrupting daily medical treatment or causing inconvenience to participants. It is hoped that such tools will be widely developed and used to allow clinical trial participants to make clinical trial decisions with greater understanding. This application did not significantly reduce decision-making conflicts. We aim in the future to add functions that focus on reducing the burden of decision making by addressing issues such as conflict and regret. Furthermore, we hope to demonstrate the effects of the decision aid on a greater range of clinical trial participants, including males and older patients.

It is difficult and time-consuming for patients to understand the complexities of clinical trials through a single discussion with doctors

and CRCs. Aids that help patients to learn about clinical trials before discussions with healthcare providers, that help communication with healthcare providers, that make it easier for patients to ask questions, and that help healthcare providers to judge the patient's understanding before the discussion would facilitate efficient and effective decision support in a limited consultation time. It is important that patients who participate in clinical trials have a full understanding of the trial to avoid trial dropout and dissatisfaction with treatment results.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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